analytikjena

Maintenance with OQ

Operational Qualification (OQ) within the scope of a maintenance for the

UV VIS Spectrophotometer

SPECORD® 210

Contents

Order no.: ---------- Customer no.: ----------

Date: ---------- performed by: ----------

Software Version Win ASPECT®: ---------- Serial number: ----------
Validation: ----------

Firmware Version: ----------

Company	
User	
Department	
Street	
Zip code, city	
Country	
Telephone	
Fax	
e-mail	

1. General Information

The SPECORD® 210 spectrophotometer is designed for the ultraviolet and visible spectral range for the measurement of absorbance (A) at defined wavelengths, over the entire or a partial spectral range and for the measurement of absorbance at fixed wavelengths versus time.

2. Definitions

2.1 Validation

Described by FDA (Food and Drug Administration, USA) as follows:

Document furnishing proof, that a defined process with a high degree of reliability will continuously yield a product that meets predefined specifications and quality features.

2.2 Verification

Defined in EN 45020: Examination of generally accepted performance data of a device or a method that are valid for all applications that can be performed with the device or method.

2.3 Qualification

Term used by Pharmaceutical Manufacturers Association (PMA, USA):

The qualification deals with the testing of instruments and software products throughout the entire life cycle of the instrument system. It may be subdivided into different phases.

- Specification Qualification (SQ)
- Production Qualification (CQ)
- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

3. Functional check of the instrument peripherals and the basic instrument functions before starting the maintenance

	complies	does not comply
Functionality of hardware and software.	☐	☐
Spectrum of a holmium oxide filter has been scanned, displayed on the screen and printed.		Date: ..... Initials: .....
Functionality of accessories.	☐	☐
		Date: ..... Initials: .....

Discovery of faults occurring in the functional check

Any faults occurring in the functional test are to be noted in writing on this page. If faults can not be repaired within the scope of the maintenance, dates for the rectification have to be entered. If no faults occur in the functional check, this should be signed by the Analytik Jena AG specialist and countersigned from the competent head of laboratory or his/her representative.

Faults occurring	Comment	Competent person	Initials	Date

Repair of faults occurring	Comment	Additional assigned service date	Competent person	Initials	Date

	complies	does not comply
The SPECORD® 210 and the included components did not show any apparent faults in the function tests performed.	☐	☐
		Date: ..... Initials: .....

Counter-read by: ..... Date: .....

4. Operational qualification, OQ

4.1 Validation of performance parameters

4.1.1 Explanation of basic adjustments

Basic adjustment of the SPECORD® 210 is performed at the manufacturer's premises. Within the scope of the maintenance with OQ, basic adjustment will be checked and at the same time proof will be furnished that the device meets the performance data guaranteed by Analytik Jena AG.

4.1.2 General notes on the maintenance followed by validation

The maintenance works include the device-specific tasks, given by Analytik Jena AG:

task	complies	does not comply
Check and adjustment of the optical path ▪ Centric illumination entrance slit ▪ Smooth-running of the grating bearings ▪ Toe of optical path and bars of the sample compartment ▪ Function of adjustable mirrors	☐	☐
Check and adjustment of the device-specific electrical Parameters ▪ Operating voltages ▪ Lamp voltage 5 V ▪ cleaning and functional check fan	☐	☐
Check of the state of the optical components ▪ D_2E –Lamp ignites ▪ function Halogen lamp	☐	☐
Cleaning of the spectrophotometer compartment	☐	☐
Check of the mechanical fastening points for firm tightening	☐	☐

The validation following the maintenance is performed user-guided with the software package „Validation of SPECORD® 210 " for the Windows-based software WinASPECT®. The printout of the result records created by software is listed in the Annex (refer to protocol names in the column **Data on protocol:** below) as accompanying documents of Operational Qualification.

Besides, the protocol and the raw data the protocol are based on will be automatically stored in computer-readable form to ensure trace ability of results.

The location of the protocols and the raw data on the PC are documented on the printout.

Copies of the measurement procedures provided by the suppliers of the standards are also included in the Section „List of accompanying documents of Operational Qualification".

4.1.3 Results of validation of performance parameters

Serial no: _____

Validated performance parameter	complies	does not comply
Zero transmittance ▪ Standard: Beam mask ▪ Standard ID: n.a. ▪ Certificate of standard valid until: n.a.	☐	☐
Baseline stability ▪ Standard: none ▪ Standard-ID: n.a. ▪ Certificate of standard valid until: n.a.	☐	☐
Baseline noise ▪ Standard: none ▪ Standard-ID: n.a. ▪ Certificate of standard valid until: n.a.	☐	☐
Baseline without correction ▪ Standard: none ▪ Standard-ID: n.a. ▪ Certificate of standard valid until: n.a.	☐	☐
Wavelength accuracy ▪ Standard: Hellma secondary standards for calibration of spectrophotometers ▪ Filter F1 (holmium filter) ▪ Catalogue Number: 666-000 ▪ Set Number: _____ ▪ Certificate of standard valid until: _____	☐	☐
Wavelength reproducibility ▪ Standard: Hellma secondary standards for calibration of spectrophotometers ▪ Filter F1 (holmium filter) ▪ Catalogue Number: 666-000 ▪ Set Number: _____ ▪ Certificate of standard valid until: _____	☐	☐
Photometric accuracy, VIS region ▪ Standard: Hellma secondary standards for calibration of spectrophotometers ▪ Filters F4 (Neutral density filter) ▪ Catalogue Number: 666-000 ▪ Set Number: _____ ▪ Certificate of standard valid until: _____	☐	☐

Counter-read by: _____ Date: _____

Validated performance parameter	complies	does not comply
Photometric accuracy acc. to Ph. Eur. ▪ potassium dichromate-solution 60 mg/l ▪ Standard-ID: ..... ▪ Charge-Number: ..... ▪ Certificate of standard valid until:	☐	☐
Photometric accuracy acc. to Ph. Eur. at 430 nm ▪ potassium dichromate-solution 600 mg/l für 430 nm ▪ Standard-ID: ..... ▪ Charge-Number: ..... ▪ Certificate of standard valid until:	☐	☐
Spectral resolution acc. to Ph. Eur. ▪ Merck toluene solution in hexane ▪ Standard-ID: ..... ▪ Charge-Number: ..... ▪ Certificate of standard valid until:	☐	☐
Stray light at 198 nm acc. to Ph. Eur. ▪ Merck potassium chloride solution ▪ Standard-ID: ..... ▪ Charge-Number: ..... ▪ Certificate of standard valid until:	☐	☐
Stray light at 220 nm acc. to Ph. Eur. ▪ Merck sodium iodide solution ▪ Standard-ID: ..... ▪ Charge-Number: ..... ▪ Certificate of standard valid until:	☐	☐
Stray light at 340 nm acc. to Ph. Eur. ▪ $NaNO_2$ solution ▪ Standard-ID: ..... ▪ Charge-Number: ..... ▪ Certificate of standard valid until:	☐	☐

Data saved in protocol: .....

	complies	does not comply
Instrument validation has been correctly performed and concluded. The device was found to comply with the performance data guaranteed by Analytik Jena AG.	☐	☐

Date: .....

Initials: .....

Counter-read by: ..... Date: .....

4.2 Conclusion of maintenance with operational qualification (OQ)

	complies	dose not comply
The maintenance with OQ has been performed and concluded correctly.	☐	☐

This provides verification that the SPECORD® 210 complies with the performance data guaranteed by Analytik

Date: .....

Initials: .....

The SPECORD® 210 is hereby released by the qualified signatories for spectrophotometric measurement.

Date: .....

Initials: .....

Counter-read by: ..... Date: .....

5. List of accompanying documents

1. Protocol
2. Copy of certificate: Standards for calibration of wavelength accuracy and wavelength reproducibility

   Catalogue -No: 666-000

   Set No:
3. Copy of certificate: Potassium dichromate solution 60 mg/l

   Standard-ID:

   Charge No:
4. Copy of certificate: Potassium dichromate solution 600 mg/l for 430 nm

   Standard-ID:

   Charge No:
5. Copy of certificate: potassium chloride solution

   Standard-ID:

   Charge No:
6. Copy of certificate: Sodium iodide solution

   Standard-ID:

   Charge No:
7. Copy of certificate: $NaNO_2$ solution

   Standard-ID:

   Charge No:
8. Copy of certificate: Toluene solution in hexane

   Standard-ID:

   Charge No:

Name technician (in block letters)	Name customer (in block letters)
Signature technician	Signature customer
Place, Date (DD/MM/YYYY)	Place, Date (DD/MM/YYYY)

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